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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,580

12/20/2007

Philip A. Beachy

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DLA PIPER LLP (US)  
4365 EXECUTIVE DRIVE  
SUITE 1100  
SAN DIEGO, CA 92121-2133

EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

07/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,580	<b>Applicant(s)</b> BEACHY ET AL.	
	<b>Examiner</b> Sheela J. Huff	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 23-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/26/00</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group IV, claim 1-22 (as they read on small organic compounds) in the reply filed on 4/23/09 is acknowledged. The traversal is on the ground(s) that Berman was filed after the priority date of the instant application and that Group I-III and V should be examiner together because they involve the same method steps and a similar restriction was not made in a related case. This is found partially persuasive therefore groups I-V are regrouped. However, the remaining groups remain restricted because the instant application only has priority to 7/15/04 (see explanation below).

The requirement is still deemed proper and is therefore made FINAL.

### ***Priority***

The instant set of claims only has priority to 7/15/04 because the provisional application does not mention all the different types of antagonists.

### ***Information Disclosure Statement***

The IDS filed 3/26/00 has been considered and an initialed copy of the PTO-1449 is enclosed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7, 10-14, 16, 18 and 21-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Berman et al Nature vol. 425 p. 846 (10/23/03).

This reference discloses the suppression of the Hh pathway in esophagus, stomach, biliary and pancreatic tumor cells by cyclopamine in vitro and in vivo. These tumors are driven by endogenous expression of Hh ligand, such as sonic hedgehog and Indian hedgehog (see abstract and entire reference).

Claims 1-10 and 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ling et al US 2003/0022819.

This reference discloses methods and reagents for the inhibition of undesired growth states that occur in cells with an active hedgehog signaling pathway. The reagents include hedgehog antagonists which include antibodies (including hedgehog antibodies), hedgehog proteins and small molecules (that read on steroidal alkaloid and derivatives thereof) and hedgehog mutants (see entire reference, [0137] +). The reference defines antagonist as a compound that inhibits activity of the hedgehog protein and inhibits ligand/hedgehog interactions ([0020]) (reads on claims 5-7 and 16). The cancer to be treated includes ([0019] and [0614]). The antibodies are directed against sonic or Indian hedgehog ([0162] +). The tumors that can be treated by the

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reference include gastrointestinal tumors ([0558]) and Example 7 specifically shows the inhibition of the growth of colon cancer cells using anti-hedgehog. The compounds can be administered orally ([0565] +).

Claims 1-3, 7, 10-14, 18 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/27135.

This reference discloses molecules that counteract the phenotypic effects of unwanted activation of the hedgehog pathway. The molecules are steroidal alkaloid of other small molecules and specifically mentions cyclopamine (page 9, 32). The diseases to be treated include pancreatic cancer and gastrointestinal tumors such as stomach and intestine (page 59-61).

Claims 1-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Dudek et al US 2004/0060568 (filed 10/13/00).

This reference discloses methods and reagents for the inhibition of undesired growth states (abnormal rate of proliferation --increased or decreased)([0092]) that occur in cells with an active hedgehog signaling pathway. The hedgehog antagonists are hedgehog antibodies, antisense nucleic acids, mutant hedgehog proteins and small molecules, such as cyclopamine ([0026], [0096], [0266] and [0168] and [0266] and entire reference). The use of the term hedgehog in the reference refers to sonic or indian hedgehog and therefore the antibodies are directed to sonic or Indian hedgehog. The cancer to be treated includes gastrointestinal tumors such as stomach intestine

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([0571]) and example 8 specifically shows inhibition of colon cancer cell growth by anti-hedgehog antibodies. Administration can be oral ([0609]).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Monday-Thursday 6am to 2pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/  
Primary Examiner  
Art Unit 1643

sjh